MERIT MEDICAL

DEC 12 2013

Section 6
510(k) Summary

General Provisions	Submitter Name:	Merit Medical Systems, Inc.
	Address:	1600 West Merit Parkway South Jordan
	Telephone Number:	(+353) 91 703700 (3061)
	Fax Number:	(+353) 91 680 104
	Contact Person:	Mark Mullaney
	Registration Number:	1721504
	Correspondent Name:	Merit Medical Ireland Ltd.
	Address:	Parkmore Business Park West Galway, Ireland
	Telephone Number:	(+353) 91 703700 (3052)
	Fax Number:	(+353) 91 680 104
	Contact Person:	Siobhan King
	Date of Preparation:	10/16/2013
	Registration Number:	9616662
Subject Device	Trade Name:	InQwire®
	Common/Usual Name:	Merit Medical Guide Wire
	Classification Name:	21 CFR 870.1330 Catheter guide wire
Predicate Device	Trade Name:	InQwire®
	Classification Name:	21 CFR 870.1330 Catheter guide wire
	Premarket Notification:	K002289
	Manufacturer:	Merit Medical Systems, Inc.
Classification	Class II 21 CFR 870.1330 Catheter guide wire FDA Product Code: DQX Review Panel: Division of Cardiovascular Devices	
Intended Use	Merit Medical guide wires are used to facilitate the placement of devices during diagnostic and interventional procedures.	

Device Description	InQwire® Diagnostic Guide Wires are intended to facilitate the placement of devices during diagnostic and interventional procedures. The guide wires have a continuous PTFE (Polytetrafluoroethylene) coated coil, inside core wire and a safety wire. The core wire is fixed at the proximal end only and extends to a specified distance from the distal end. The distal segment of the core wire has a profiled taper. The core wire enhances the stiffness of the guide wire. The safety wire extends the full length of the guide wire and is welded at both the distal and proximal end. The safety wire is designed to provide integrity and ensures that the guide wire components remain together. The InQwire® Diagnostic Guide Wires are offered in 0.035 inch or 0.038 inch outer diameter with different tip configurations (straight or J-tip), single ended or double ended (either end of the wire can be placed into the patient), standard or firm shaft, and are available in lengths from 50cm to 260cm. The wire is placed inside a loop flush dispenser, also referred to as a hoop. The dispenser has a female Luer connection which facilitates solution flushing through the hoop to hydrate the guide wire. The guidewires are secured in the hoop dispenser by a locking J-tip straightener. This modification details a supplier process change relating to removal of perfluorooctanoic acid (PFOA), used in the manufacture of the PTFE (Polytetrafluoroethylene) coating. More specifically PFOA is a processing aid used for the polymerization process of PTFE, which is flashed off during the oven curing process and therefore not part of the finished InQwire® Diagnostic Guidewire. Due to environmental concerns relating to PFOA, the U.S. Environmental Protection Agency has instructed that all processors of PTFE no longer make, buy or use PFOA(2010/2015 PFOA Stewardship Program). PFOA material is used in the manufacture of both the intermediate layer and top layer of the PTFE(Polytetrafluoroethylene) coating.
Comparison to Predicate	Technological characteristics of the subject Merit InQwire® Diagnostic Guide Wire are substantially equivalent to those of the predicate, the Merit InQwire® Diagnostic Guide Wire [K002289]. The difference between the devices relates to the guide wire coating. The guide wire design and indications remain unchanged.

Safety & Performance Tests

No performance standards have been established under section 514 of the Food, Drug and Cosmetic Act for these devices. Performance testing of the subject Merit InQwire® Diagnostic Guide Wire was conducted based on risk analysis. A battery of testing was conducted in accordance with protocols based on requirements outlined in guidance's and industry standards and these were shown to meet the acceptance criteria that were determined to demonstrate substantial equivalence.

Where appropriate, the tests were based on the requirements of the following documents:

- FDA guidance Coronary and Cerebrovascular Guide Wire Guidance January 1995.
- ISO 11070:1998, *Sterile Single-Use Intravascular Catheter Introducers.*
- ISO 11135-1:2007 *Sterilization of health care products-Ethylene oxide- Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices.*
- ASTM F1980-07 *Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices*
- ISO 10993-1:2009, *Biological Evaluation of Medical Devices Part 1: Evaluation and Testing within a risk management process*, and the FDA Modified ISO 10993 Test Profile FDA Memo G95-1.

The Merit InQwire® Diagnostic Guide Wire was compared to the predicate device for various performance attributes that support substantial equivalence of the device. The difference in coating between the modified device and the cleared device [K002289] has raised no new issues.

The following is a list of all significant testing that was successfully completed:

- Surface
- Coating Adherence/Integrity
  - Fracture Test
  - Flexing Test
  - Coil Lubricity Test
- Catheter Compatibility
- Biocompatibility

All test results were comparable to the predicate devices and the subject Merit InQwire® Diagnostic Guide Wire met the predeterminded acceptance criteria applicable to the safety and effectiveness of the device. This has demonstrated the subject device is substantially equivalent to predicate device.

Summary of Substantial Equivalence	Based on the Indications for Use, design, safety and performance testing, the subject Merit Medical InQwire® Diagnostic Guide Wire meets the requirements that are considered essential for its intended use and is substantively equivalent to the predicate device, the cleared Merit InQwire® Diagnostic Guide Wire manufactured by Merit Medical Systems Inc.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

December 12, 2013

Merit Medical Systems, Inc.
Ms. Siobhan King
Parkmore Business Park West
Galway, Ireland

Re: K133230
Trade/Device Name: InQwire Diagnostic Guide Wire
Regulation Number: 21 CFR 870.1330
Regulation Name: Guide Wire
Regulatory Class: Class II
Product Code: DQX
Dated: November 7, 2013
Received: November 12, 2013

Dear Ms. King:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman -S

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 5
Indications for Use Statement

510(k) Number (if known): _____

Device Name: Merit InQwire® Diagnostic Guide Wire

Indications for Use:

Merit Medical guide wires are used to facilitate the placement of devices during diagnostic and interventional procedures.

Prescription Use [X] AND/OR Over-The-Counter Use [ ]
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Bram D. Zuckerman -S
2013.12.12 16:23:45
-05'00'